Tactile and kinaesthetic stimulation in preterm neonates with hyperbilirubinaemia

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SYNOPSIS SUBMITTED

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Doctor of Philosophy

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Certificate

This is to certify that the PhD thesis synopsis / protocol on, **"Tactile and kinaesthetic stimulation in preterm neonates with hyperbilirubinaemia"** has been done by Saumya Kothiyal, 1820748, under my supervision. I am satisfied with the work presented by the candidate towards the partial fulfillment of Doctor of Philosophy (PhD) in Physiotherapy. This is an original work submitted only to Maharishi Markandeshwar (Deemed to be University), Mullana – Ambala, Haryana and is free from plagiarism at the time of her submission.

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Abstract:

Background: Hyperbilirubinaemia is the commonest problem seen in neonates, owing to severe complications in lifetime.

Objective: Objective of the study is to evaluate the effectiveness of massage therapy and tactile stimulation in neonates with hyperbilirubinaemia.

Methods: The study design of the study is pre-test – post-test experimental design. Convenience Sampling will be used for recruiting the neonates. In study neonates will be selected according to the selection criteria and will be allocated into two groups in 1: 1 ratio using block randomization and will be allocated to two groups using SNOOZE, Group 1 – neonates will receive tactile and kinaesthetic stimulation for 15 minutes for 3 consecutive days, 1 hours after feed twice daily along with Phototherapy, Group 2 – Phototherapy alone will be given. Total serum bilirubin and weight gain will be assessed as outcome measure daily once. Transcutaneous bilirubin will be assessed before and after every intervention.

Discussion: Impact of tactile and kinaesthetic stimulation in addition to phototherapy will be revealed at the end of the study.

Trial registry number: The trial has been registered in clinical trial.gov.in with unique id no. MMDU/IEC/2153 and UTN trial no. U1111-1269-9876.

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Keywords: Bilirubin, Hyperbilirubinemia, New-born, Phototherapy

1.0 Introduction

Hyperbilirubinaemia in new born is a condition characterized by serum bilirubin levels more than 5 mg/dl that is visible as yellowish coloration of skin, sclera and mucous membrane that clinically progresses from face to lower extremities with appropriate proportion to increasing levels of serum bilirubin.[1] Bilirubin is produced by lysis of haem component of red blood cells in spleen to unconjugated bilirubin.

In Neonatal Intensive Care Unit (NICU), the environment is stressful for child also physical separation from mother leads in increasing it.[2] About 60 -80 % of neonates presents with idiopathic Hyperbilirubinaemia and is the most common cause of hospitalization of neonates in first week of life. Neonatal jaundice results from an imbalance between the production and excretion of bilirubin, due to immature liver of new born as it is not fully developed to cope up with the rhythm needed for the excretion of bilirubin it is elevated in the blood and rapid breakdown of red blood cells. The bilirubin gets excreted from the body through stool and urine.[3]

Hyperbilirubinaemia in neonates may be due to various reasons and is classified as, physiological jaundice that appears 24 -72 hours after birth with peak of total serum bilirubin more than 6 -7 mg/dl on 3-4 postnatal day in term and 7th day in preterm neonates and is resolved on 10-14 days of life itself, but if not resolved the bilirubin level is increased in blood, termed as bilirubin toxicity and could lead to neurodevelopmental deformities or other anomalies such as deafness and mild mental retardation[4] as unconjugated bilirubin is capable of crossing blood brain barrier.[5] Etiology of Physiological jaundice is that the immature hepatic glucuronosyl transferase enzyme that helps in conjugation of bilirubin and facilitates its excretion from the body.[6]

Bilirubin levels may also be affected by substances present in breast milk therefore causing breast feeding jaundice, thus prolonging the duration of physiological jaundice in neonates by increasing the enterohepatic circulation.[2] Late onset of breast feeding jaundice occurs after 6 postnatal day and may persist for more upto 1 – 3 months, with bilirubin level rise from 12 to 20 mg/dl that should be decreased about 3 mg/dL if breast feeding is stopped for 48 hours.[6] Early jaundice, also known as pathological jaundice in neonates starts within 24 hours of birth with 0.5mg/dl increase in total serum bilirubin every hour and hepatosplenomegaly is also seen in pathological jaundice and bilirubin levels may exceed > 18.71 mg/dL whereas in physiological jaundice it may not exceed more than 14.62 mg/dL,[3] It commonly occurs due to isoimmunization of or other significant cause of hemolysis. G6PD deficiency jaundice present is starts after 48 hours and it could be present as non – hemolytic jaundice. [7]

The guidelines of National Institute for health and Clinical Experience (NICE) recommends keeping track of bilirubin levels in neonates after 24 hours of age with visible yellowish color of skin. Total Serum Bilirubin (TSB) and Transcutaneous Bilirubin (TcB) levels can identify the that in the neonates with TSB level higher than 95th percentile of age.[8] Severe Hyperbilirubinaemia TSB > 20 mg/dl would lead to bilirubin encephalopathy or kernicterus leading to neurodevelopment delay. Although it is a self-limiting condition which is improved once the bilirubin levels are maintained to normal. Although it does not increase mortality but its potential toxicity may lead to severe morbidities.[9]

Hyperbilirubinaemia (bilirubin levels < 30 mg/dl) may lead to severe complications such as Kernicterus also known as bilirubin encephalopathy, is the most common complication of Hyperbilirubinaemia in neonates leading to neurodevelopmental disabilities in future life i.e. 10 % of mortality and 70% of morbidity. Clinically, in neonates bilirubin encephalopathy leads to hypotonia, poor sucking and being lethargic initially then its progression is marked by

hypertonia mainly of extensor muscle group and then gradually and after several years children have developmental and motor delays in form of choreoathetoid cerebral palsy. [10]

To prevent kernicterus and its sequelae, an assessment of bilirubin levels during first week of birth of new born is conducted as per the guidelines given by American Academy of Paediatrics (AAP)[11], risk factors of bilirubin encephalopathy may include, preterm neonates with birthweight less than 1000g, APGAR score <3 at 5 minute of age, Rh incompatibility, serum albumin < 2.5 g/dl, sepsis, previous sibling treated with phototherapy.[12] Screening of bilirubin level is done in neonates at 48 to 72 hour after birth, for combating the risk of Hyperbilirubinaemia. AAP suggested best method total serum bilirubin (TSB) measurement as the best method for assessing bilirubin levels in blood. Transcutaneous bilirubin measurement is also an efficient method of screening the bilirubin levels and also avoid repeated blood samples.[13]

Previous literature have suggested phototherapy as the mainstay treatment for the management of neonatal hyperbilirubinaemia to reduce the bilirubin levels in neonates with hyperbilirubinaemia, it has also reduced the need of exchange therapy.[14] There may be various short term and long term side effects of phototherapy including molecular alteration, thermal or hydroelectric imbalance, dehydration, skin lesions or bronze baby syndrome which may increase the effect of kernicterus and long term side effects may include neoplasm.[15] Therefore, duration of phototherapy neonates need to be reduced to avoid the side effects of phototherapy.

Previous literature has proved the positive effects of massage therapy beneficial in reducing bilirubin levels, Although, different types of massage therapy have been introduced and have shown a tremendous role in eliminating bilirubin levels and reducing the duration of phototherapy.[16,17]

Also there are evidence of massage along with kinaesthetic stimulation i.e. tactile/ kinaesthetic stimulation helps in improving the weight gain in preterm neonates, possibly by improving the vagal tone in neonates and therefore enhancing the gut mobility associated with increased stool frequency and thereby fast elimination of bilirubin from body.[17] The objective of this study is to combine massage therapy along with movement of joints of neonates, i.e. to observe the effect of tactile and kinaesthetic stimulation in reducing bilirubin levels in neonates with Hyperbilirubinaemia.

1.1 Need of the study

Previous study has proved tactile and kinaesthetic stimulation have resulted in weight gain in preterm neonates, but to best of authors knowledge no strong evidence was found to reduce bilirubin levels in neonates. Therefore, this study would help to combat the effectiveness of tactile and kinaesthetic stimulation on neonates with hyperbilirubinaemia.

1.2 Research Question

Does Massage therapy along with Kinaesthetic stimulation as an adjunct with phototherapy is helpful in reducing bilirubin levels?

1.3 Hypothesis

1.3.1. Null Hypothesis – There is no significant difference observed in bilirubin level and weight gain in preterm neonate after application of tactile and kinesthetic stimulation between experimental and control group.

1.3.2. Alternative Hypothesis –A significant difference observed in bilirubin level, weight gain after application of tactile and kinesthetic stimulation between experimental and control group.

2.0 Review of Literature

2.1. Neonatal jaundice

According to the literature, Hippocrates described jaundice for the first time in 400 BC. In 1724, the difference between true jaundice and icteric trace in neonates was observed by Juncker, also in 1903 the term kernicterus term was labelled to a condition when bilirubin was found in basal ganglia in neonates with severe hyperbilirubinaemia.[6]

In neonatal jaundice there is an imbalance between the production and excretion of bilirubin.[3] It is one of the major cause for increase in hospital stay or readmission of new born to hospital after 24 hours, Neonates with serum bilirubin levels above 6mg/dL in 20 ± 4 hours and 9 mg/dl in 44 ± 4 hours gets discharged from hospital after 24 to 48 hours to prevent readmission of neonates after discharge.[18]

2.2. Pathogenesis

As the life span of RBC is very short in neonates, they are phagocytosed by macrophages and hemoglobin is released that further decomposed to unconjugated bilirubin, as in normal pathway the unconjugated bilirubin is converted into water soluble conjugated bilirubin, and then secreted into small intestine, where it is hydrolyzed by intestinal flora into bilinogen which is excreted into feces, and 10 % of which is reabsorbed into circulation an released back into intestine along with bile, thus forming enterohepatic circulation , as the flora of neonates have a very low bacterial count, bilirubin entering the small intestine is not metabolized and directly excreted into feces, leading to disruption in liver uptake, or increase in plasma bilirubin which leads to abnormal processing of liver thereby equilibrium between production and excretion of bilirubin is reduced which may lead to neonatal hyperbilirubinaemia.[19]

2.3. Complications of Neonatal jaundice

Preterm neonates with severe hyperbilirubinaemia (serum bilirubin levels more than 20 -26 mg/dL) are more susceptible to Bilirubin Induced Neurological dysfunction (BIND), which may lead to bilirubin encephalopathy or kernicterus resulting from immature neonatal liver having reduced ability to take up, conjugate and excrete bilirubin therefore free bilirubin can cross the blood brain barrier and gets deposited in globus pallidus, thalamus, cerebellum, thalamus hippocampus or other part of the brain.[19] A moderate increase in unconjugated bilirubin levels would affect the hippocampus and its prolonged exposure would lead to learning disabilities in neonates.[20] The clinical manifestations of bilirubin encephalopathy may range from mild to severe signs including reversible signs of lethargy, changes in muscle tone, increased latency of brain auditory evoked responses (BAER) to irreversible signs visible in early life such as opisthotonos, seizures and even mortality, and late permanent changes including choreoathetoid cerebral palsy, hearing loss, epilepsy, speech and motor dysfunctions.[21,22]

2.4. Pharmacological Management of Hyperbilirubinaemia

Drugs such as Metalloporphyrin targets for the inhibition heme oxygenase, few drugs are responsible for increasing conjugation of bilirubin such as Phenobarbital and clofibrate. Agents that decreases entero-hepatic circulation bilirubin, Oral charcoals, Agar etc.[23]

2.4.1. Zinc Therapy

A study was conducted to find out the efficacy of oral zinc salt (zinc gluconate) in neonates with hyperbilirubinaemia as zinc have shown its role in reducing the serum total bilirubin (STB) levels by inhibiting enterohepatic circulation. It was a double blinded, placebo-controlled, randomized trial, in the study neonates with STB $\geq$ 6 mg/dL 24$\pm$ 6 h of age. The neonates enrolled in the study were divided into two groups, neonates in intervention group

(n=145) received 5 mg dose of zinc gluconate twice daily from 2nd to 7th day and neonates were examined 12 hourly till 3 days of age. Results of the study found that out of 145 neonates enrolled in intervention group incidence of neonatal jaundice was 26% whereas in placebo group 27% neonates out of 141 had incidence of jaundice. Mean duration of phototherapy in intervention group was 22.8±19.4 hours and in placebo group it was 35.6 ± 16.1hours. This study concluded that the dosage of 10 mg oral zinc gluconate daily reduces the duration of phototherapy in neonates with hyperbilirubinaemia.[24]

A double-blinded clinical trial was conducted with 60 preterm neonates withing age 30 to 36 weeks and 6 days and birth weight between 1500 g to 2500 g suffering from neonatal jaundice, and excluding neonates with ABO incompatibility, mechanical ventilation, Coombs's test positive, G6PD deficiency, hemolysis or infection. Neonates were allocated into two groups, where neonates in one group received zinc sulfate along with phototherapy whereas in other group neonates received placebo (containing sucrose syrup) was given with phototherapy and was administered in every 6 hours until phototherapy was required. Phototherapy was given using tusan device with four Philips lamp at distanced of 25 cm from the baby with minimum intensity of light upto 10μW/cm^2/nm. Bilirubin levels were assessed at baseline, after 6 h and after 24 h of giving intervention and were found to be 12.2±71.67mg/dL,11.2 ±26.62 mg/dL and 9.2 ± 45.83 mg/dL respectively in experimental group and 10.2± 35.24 mg/dL, 9.2±86.32 mg/dL, 8.2±44.10 mg/dL in control group. A significant reduction in level of bilirubin was noted within 24 h of giving zinc. The mean bilirubin level change assessed before and after 6 h of intervention i.e -1.3 ± 45.23mg/dL, before and 24 h after intervention change was 3.2± 26.78 mg/dL before and after 48 h change found was -4.2±89.76 mg/dL. Therefore, as the conclusion of the study it was recommended to use zinc sulphate (1cc/kg) in preterm neonates with neonatal jaundice.[25]

2.4.2. Probiotic Therapy

A randomized controlled trial was conducted to evaluate the effect of probiotic therapy on serum bilirubin levels in term neonates with Hyperbilirubinaemia, in the study 150 neonates were recruited those were admitted in hospital for phototherapy and they were allocated into two groups, experimental and control and in both the groups neonates received conventional phototherapy by phototherapy device in experimental group along with oral probiotic (Pedilact, Zisttakhmir) was given 10 drops/day until discharged from the hospital. Serum bilirubin levels was used as the primary outcome and time needed for phototherapy and length of hospital stay was measured a secondary outcome. Mean Serum bilirubin levels (SBL) at baseline in intervention and control group was 16±1.9 mg/dL and 16±1.9 respectively and was decreased in 24h, 48h, 72h to 13.73±1.72 mg/dL, 10.92±1.87mg/dL and 10.25±1.32mg/dL in intervention group and13.66±1.91mg/dL, 11.01±1.69mg/dL,10.09±1.38mg/dL in control group. The study concluded that there was no effect of prebiotic along with phototherapy in reducing the serum bilirubin levels in neonates with Hyperbilirubinaemia.[26]

2.5. Screening

Early screening is necessary to determine the bilirubin levels in neonates to prevent bilirubin toxicity. A combination of screening and risk factors can determine risk factor of neonatal jaundice. Total serum bilirubin levels and transcutaneous bilirubin is universally used to identify the levels of bilirubin and risk factors more than 95 percentile depending upon the age. Screening helps in identifying whether infant needs phototherapy or exchange therapy.[8]

2.6. Non-Pharmacological Management of Hyperbilirubinaemia

2.6.1. Phototherapy

Phototherapy is being used as the treatment of neonatal Hyperbilirubinaemia since 1958, when very first phototherapy unit was incorporated in Rochford Hospital in Essex, England where a

nurse noticed that yellowish color fades away if baby was exposed to sunlight, therefore an artificial light source was used in instead of natural sunlight to reduce bilirubin levels in neonates. Reduction in total serum bilirubin levels after initiation of phototherapy is variable in neonates but a 6 % to 20% decrease is expected.[8]

Phototherapy helps in reducing the bilirubin levels and preventing its accumulation in brain, it has also reduced the need of exchange transfusion in Hyperbilirubinaemia, as soon as neonate is exposed to the light source photoisomerization begins instaneously.[27]Previous literature have suggested the phototherapy works on two types of reaction that occurs when bilirubin is exposed to the photons i.e process of photo-oxidation and isomerization that leads to partial oxidization of bilirubin during exposure of neonates to light and the oxidized products are excreted out in urine, also photo isomers cannot cross the blood brain barrier.

According to American Academy of Pediatrics, Gallium nitride LEDs that emits blue florescent light with frequency between 460 nm - 490 nm (blue green region) is most effective in reducing bilirubin levels and is preferred mainly because bilirubin absorbs maximum light on the blue part of spectrum, exposure of 100% of body surface of neonate is not possible as eye mask for covering the eyes and diaper to cover genitals, therefore the posture needs to be changed after every 2 to 3 hours and combination of more than one phototherapy device is recommended for maximum exposure of neonate to light.[14] Earlier blue and green lights lamps were used for phototherapy but bilirubin molecules absorbs more readily the blue light, also skin was exposed to UV light, activating the pro-inflammatory pathway thus increasing the production of inflammatory factors and triggers autoinflammatory response, but in addition UV light may mutate the gene thus increasing the risk of cancer.[19]

A randomized controlled trial was conducted to observe the double phototherapy device is more effective and helps in faster reduction of bilirubin levels in neonates with

Hyperbilirubinaemia, in this study eighty-three neonates with gestational age > 33 weeks and body weight > 1800 g, 24 hour of age and having a rapid increase in total serum bilirubin levels were recruited in the study. Neonates were allocated into, Group1 receiving single blue LED light and Group 2 receiving double blue LED light, all infants received phototherapy for 24 hour, except during feeding, the results have shown that there was a faster reduction in total serum bilirubin levels in group receiving double phototherapy i.e TSB reduced by 58 % after 24 hours of Phototherapy treatment with lower level of radiance as compared to those neonates receiving single phototherapy 47% reduction in TSB levels after 24 hours phototherapy.[28]

A randomized controlled trial conducted suggested that there is a significant more reduction in bilirubin levels of neonates with hyperbilirubinaemia if there is shorter distance between light source and neonate. The study compares phototherapy given at distance of 20 cm to neonates with light intensities of 13– 14 μW/cm^2/nm with a light intensity of 6 -7 μW/cm^2/nm given at 40 cm distance between neonate and light source using blue light with wavelength of 452 – 475 nm and noted that there was approximately 2 times improvement in neonates who were given phototherapy at 20 cm distance. For this study 63 term neonates and preterm neonates with bilirubin levels > 10mg/dL and >12 mg/dL respectively were enrolled and were randomly assigned to phototherapy at 20 cm distance or to group in which phototherapy will be given at 40cm. Neonates were put in bassinets naked with genitals covered with diaper and eyes shielded, bilirubin levels and light intensity were measured at baseline in 12 hours and in 24 hours after phototherapy, thus result showing a decrease in mean serum bilirubin levels in group that received phototherapy at distance of 20 cm, 3.8(0.71)mg/dL, 3.8 (0.77) mg/dL, in 0-12 and 12- 24 hours respectively, whereas comparatively there was reduction of mean serum bilirubin levels were 0.1(0.17) mg/dL, 1.9(0.82) mg/dL in 0-12 and 12- 24 hours respectively. Thus concluding that phototherapy at distance of 20 cm is more effective than phototherapy given at 40 cm distance.[29]

2.6.2. Exchange therapy

A previous study determined the indication, need and adverse effect of exchange therapy in neonates with hyperbilirubinaemia, a retrospective study conducted for two years in a tertiary hospital. Neonates with higher bilirubin levels more than 5 mg/dL or with clinical features receives exchange therapy along with standard hospital care with double volume exchange therapy, The study reported that administration of intravenous immunoglobulin has led to reduced requirement of phototherapy, Exchange transfusion and reduced the duration of hospital stay.[30]

2.6.3. Side effects and Risks of Phototherapy

Various short term and long-term adverse effects of phototherapy have been reported it requires mother infant separation, blood sample for measuring TSB levels and prolonged hospitalization that increases the chances of emotional distress in parents as well as neonates, thus increasing frequency of episodes of crying in neonates undergoing phototherapy which may be associated with changes in circadian rhythm during phototherapy. Also there have been evidence of about 26.4% moisture loss in neonates during phototherapy leading to dehydration. Formation of rashes and due to more secretion of calcium in urine, hypocalcemia may develop in neonate undergoing phototherapy.

In Bronze baby syndrome there is noticeable skin changes in neonates, associated with irregular pigmentation resulting from phototherapy. Late adverse effects would include DNA damage, tumors and also infant mortality.[19] Literature have also proved an association of elevated bilirubin levels and phototherapy may increase the risk autism (social and communication deficit).[31]

2.6.4. Kangaroo Mother Care (KMC) along with phototherapy have reduced the duration of phototherapy in neonates with hyperbilirubinaemia. An observational study, was conducted on

fifty neonates with physiological jaundice and breast feeding- associated jaundice, gestational age between 35 to 40 weeks, the study was conducted with the aim whether the duration of phototherapy in neonates getting (KMC). Recruited neonates were divided into two groups, 28 neonates were in intervention group and received KMC their parents were able to visit NICU 3 times daily and skin to skin contact was maintained between babies and their mother for one hour per session and 22 were in control group who received standard care only. In intervention group babies were cared for 1 hour and neonate were kept vertically under the clothes between the mother's breast whereas neonates in control group were those whose mothers could not stay in hospital and were given continuous phototherapy. Neonates in KMC group with peak bilirubin levels 15.30±1.90mg/dL recovered earlier i.e 68.14± 24.32 hours as compared neonate in control group with peak bilirubin level 15.30±1.90mg/dl they recovered in 100.86± 42.26 hours. Therefore, study concluded that the group that received KMC reduced bilirubin levels in shorter time as compared to neonates in control group.[32]

2.6.5. Massage therapy

Previous literature has proved that massage therapy reduce bilirubin levels by either of the two mechanisms, massage therapy leads to vagal stimulation leading to increased vagal activity increasing the gastric mobility which leads to increase in bowel movement and frequency of stool which further to decreases enterohepatic circulation of bilirubin, another proposed mechanism is that massage can increase the flow of lymph which increases the flow of blood, lymph and tissue fluid in the subcutaneous tissue, which increases the bilirubin excretion.[17]

A study was conducted in which 40 preterm stable newborns (day 1 after birth) from a tertiary hospital in Iran were recruited and were allocated into two groups one in which they provided massage therapy from day 1st to 4th postnatal day for 20 minutes using almond oil after thoroughly washing hands and, in another group, they provided conventional phototherapy and

both the group received regular Neonatal ICU care. Massage started at periorbital and cheek region then sliding down to chest and external side of upper and lower limb, then abdomen was massaged gently with both thumbs in half circle, proceeding to back massage was done by sliding both hands on two sides of vertebra from neck to buttock. Transcutaneous bilirubin was recorded on the first day before massage and after on 2nd and 4th day after intervention in which the mean of three readings were taken once from forehead and twice from thorax. The mean stool frequency was higher in newborns in massage group as compared to control group also the i.e on Day 1 transcutaneous bilirubin levels were 5.60 ± 1.14 mg/dL for control group and 5.65 ± 1.09 mg/dL mean bilirubin level measured after 3rd and 4th day of treatment (8.05±1.39 mg/dL, 9.90± 1.30 mg/dL respectively) was significantly considerably reduced as compared (9.75±1.61 mg/dL,12.00 ±1.50 mg/dL) to control group with significant difference between 1st to 4th day was 4.79± 1.84 mg/dL in massage group and 7.56±1.36 mg/dL in control group . Therefore, the study concluded massage can prevent excessive bilirubin elevation and reduces the need of phototherapy in neonates.[16]

A study was conducted in which 56 neonates with jaundice were recruited, and were allocated 29 in control group and 27 in massage group. The study aimed to evaluate the effectiveness of massage on neonatal jaundice along with phototherapy. Massage technique was performed in accordance with the International Association of Infant Massage (IAIM) to the neonates in massage group twice a day starting on the first day of phototherapy, using sweet almond oil for 15 – 20 mins/session, during this time phototherapy was stopped. Massager started massage using thumb from preorbital area and check region, then chest region was massaged, then abdomen was massaged and semicircles were formed with confirmation of colon. Baseline characteristics of neonates in interventional and control group had no significant difference. Significant improvement in microbilirubin levels of neonates was seen from Day 1 to Day 3 in control group (15.6 ± 0.9 mg/dL to 12.2 ± 1.8 mg/dL) and treatment group (15.6 ± 0.9 mg/dL

to 10.8± 0.9 mg/dL). Also, present study concluded that the frequency of defecation was higher in neonates who received massage therapy along with phototherapy as compared to neonates in control group receiving only phototherapy. Whereas the benefits of massage therapy in reducing the bilirubin levels remains uncertain.[33]

A study was conducted on healthy full term new born with aim to find out the efficacy of gentle of massage in full term neonate, in intervention group which neonates were given baby massage for 15 – 20 mins twice daily from first to fifth postnatal day, 1 hour after of morning and midday feed from first to fifth day. Neonates were recruited in were allocated into treatment (n=22) and control group (n=22). Outcome measure used were stool frequency, transcutaneous bilirubin levels measured first day to fifth day and serum bilirubin values measured in fourth day postnatally. Massage was done by applying massage oil according to touch therapy by Field et al in 1986. Transcutaneous bilirubin levels were 4.4 ± 1.4 mg/dL in control group and 4.4 ± 1.1 mg/dL in intervention group and changes in control group on second, third, fourth and fifth day was 8.2 ± 1.7 mg/dL, 10.6 ± 1.8 mg/dL, 11.7 ±1.4 mg/dL, 1.6 ±2.2 mg/dL respectively. Whereas in treatment group the changes were 7.2 ± 1.3 mg/dL, 9.1 ± 1.9 mg/dL, 9.9 ±2.9 mg/dL, 3.5 ±3.1 mg/dL respectively and total bilirubin values on 4^{th} day was 11.7 ± 2.8 mg/dL in treatment group and 13.7±1.7 mg/dL in control group. Therefore, it suggests that bilirubin levels can be reduced using baby massage as early stage after birth of new born.[34]

Massage therapy along with phototherapy reduces the bilirubin levels in patients with neonatal jaundice. A previous study was done in which 134 patients were recruited and randomly assigned to either intervention (massage combined with phototherapy) or controlled group (phototherapy only). Gentle Massage was given for 15 -20 mins twice daily by the mother using baby oil, started initially from face then cheek area using thumb continuing to chest area and semicircular movement given at abdominal region, moderate pressure massage was given to upper and lower limb and spine was massaged using two thumbs from neck to buttocks. each

day total serum bilirubin levels were measured Day 1 to Day 4. the values for each day bilirubin levels for treatment group from day 1 to day 4 were 18.44±1.9 mg/dL,13.52 ± 2 mg/dL, 9.66±1.78 mg/dL, 6.94±0.59 mg/dL respectively which shows better improvement in bilirubin levels as compared to control group from day 1 to day 4 18.33±1.84 mg/dL, 14.93±1.64 mg/dL, 11.62±1.98 mg/dL, 9.36±1.41mg/dL respectively. Therefore, the study proved massage therapy combined with phototherapy is effective in reducing the level of total bilirubin in less than 4 days.[35]

A single blinded randomized controlled trial was conducted in 2013 with the aim to investigate the effect vimala massage on neonatal physiological jaundice starting from their first day of birth. New born were selected according to the selection criteria and were randomly assigned to intervention and control group, 15 minute session of Vimala massage was given to healthy newborns weighing 2500 – 4000 g with bilirubin levels less than 5 mg/dL, massage was given in two phase in first phase it was given in supine position, face was massaged from center of forehead to sides of face, over chest it was carried out across ribs, arms and wrist were massaged in rotatory movement then abdomen from and in second phase in prone position massage was given, both thighs were massaged towards knee and then to feet in Indian milking movement in second phase it was given in prone position and massage was given in tangential position to infants back, from neck to waist with both hands moving in opposite directions. Primary outcome used was transcutaneous bilirubin, meconium frequency and were measured every morning during 9 -10 am. Transcutaneous bilirubin levels measured from Day 1 to Day 4 in interventional group was 0.00(0.00,0.01) mg/dL, 4.1(3.1,4.6) mg/dL, 6.5(5.8,7.4) mg/dL, 8.2 (5.4,10.3) mg/dL as compared to control group 0.00 (0.00,0.01) mg/dL, 4.6 (2.9,5.5) mg/dL, 6.5(3.2,7.8) mg/dL, 6.25 (3.0, 9.3) mg/dL. The study concluded that after the intervention of 4 days although significant difference in TSB was not seen but a significant the trend of increase was lower in intervention group as compared to control group.[36]

2.6.6. Tactile and Kinaesthetic Stimulation in preterm infants

Previous literature have suggested that massage therapy and kinaesthetic stimulation improves the growth, helps in weight gain and improves bone mineralization in preterm neonates, a randomized controlled clinical trial was conducted, in which 147 healthy preterm neonates with birth weight <1500 g and or gestational age ≤ 32 weeks, and were selected and allocated into control group, massage therapy group, or massage with kinaesthetic stimulation (M/ KS). In massage group massage for which consists of six strokes 10 sec in prone position from head to crown to neck to shoulder from middle of arm to back upto waist then legs from thigh to ankle and in arm upto wrist. In another group kinaesthetic stimulation was given in addition to massage therapy in supine position and both elbow and knee movement is done. At the baseline weight of the neonates were 1174±30g in control group, 1216±44g in group receiving massage and 1263±194 g in kinaesthetic group, which was improved to 2298±82 g in massage group, 2176±88g in massage group and 2375±93g in group receiving massage and kinaesthetic stimulation. The study concluded that maximum weight gain was observed in group receiving massage therapy along with kinaesthetic stimulation.[37]

Pressure of applying massage plays an important role in neonates, A randomized controlled trial was conducted with the aim to observe the improvement in various parameters in neonates who received moderate pressure massage versus those received light pressure massage. Sixty - eight pre term neonates with mean gestational age of 30 weeks were recruited and randomly assigned into two groups one receiving light pressure and other receiving moderate pressure massage. Intervention was given for 15 mins daily for 5 days approximately after 1 hour of feed given to neonate. In both the groups the intervention was given in three phase each of 5 mins. First and last phase consists of massage therapy and in middle 5 min phase kinaesthetic stimulation was given; similar procedure was followed for both the groups where moderate pressure was given in Group 1 and light pressure massage was given in Group 2 and middle

phase of kinaesthetic stimulation remains same in both groups. The results of the study concluded that in neonates those received moderate pressure massage, there was a higher weight gain in neonates, were more calm and the heart was lower as compared to those receiving light pressure massage therapy.[38]

2.7 Mechanism of action

Previous literature has suggested that tactile and kinaesthetic stimulation leads to vagal stimulation that leads to improvement in gut mobility and gastric activity, and have shown a faster weight gain in preterm neonates. It also improves the sleep cycle of neonates resulting in more relaxed neonate and lower expenditure of energy and which would also be a factor in improvement of weight that helps in early discharge of neonate from hospital.[37] Previous study have reported that moderate pressure massage therapy have increased vagal tone in neonates with hyperbilirubinaemia which increases the gastric mobility thus increasing the stool frequency, as increase stool frequency is associated with reducing bilirubin levels. Also another proposed theory is that massage therapy leads to increase blood and lymph flow thus increasing excretion of bilirubin and reducing it level in blood.[17]

2.8. Outcome measure

Transcutaneous bilirubinometer is being used since 1980s for measuring the bilirubin levels. Although serum bilirubin measure remains the gold standard of measuring total serum bilirubin levels in neonates, Transcutaneous Bilirubin is measured to access the bilirubin levels as it is easier and more convenient method and decreases the blood samples. A randomized controlled trial was conducted in which 430 neonates with gestational age $\leq$ 32 weeks with age > 24 hours to < 8 days after birth were recruited into two groups with 1:1 allocation, In intervention group consisted of application of six strokes, lasting for 10 second each head from crown neck , shoulder from middle of back to arm, back from neck to arm, neck to waist leg top of thigh to

ankle in massage and kinaesthetic stimulation with addition to kinaesthetic stimulation consisting of turning baby into supine position and six movement of each elbow and each knee. Sternal TcB was recorded and in control group visual assessment of neonates was done by observing the color of skin and accordingly decision of collecting blood sample for measuring serum bilirubin was taken, the result of this study shows that there was reduction of 38.5 % in blood sample being drawn as TcB is painless and easy to perform it is advisable to use TcB in neonates with jaundice admitted to hospital.[39]

Validity of bilirubinometer has been determined with a study that was conducted on 122 neonates with 1 week of age, both sex having visible yellowish coloration due to Hyperbilirubinaemia. Blood samples were sent to laboratory for total serum bilirubin and also transcutaneous bilirubin was measured using BiliCheck jaundice meter. The study found a good correlation of coefficient ($p<0.01$) was found between total serum bilirubin and transcutaneous bilirubin at baseline, also while measuring bilirubin levels it should be taken into consideration that values of total bilirubin levels and transcutaneous bilirubin differs after phototherapy intervention.[40]

Previous literature have proved that there is a correlation between transcutaneous bilirubin and total serum bilirubin, therefore bilirubinometer can be used in very preterm babies as alternative of invasive measurement of bilirubin.[41]

Table 2.9. Summary of the published studies included in this review

Authors/ Year	Sample	Population /Intervention	Outcome measures	Conclusion
Rana N et al	N= 294 zinc group = 148 placebo group =146	Neonates with gestational age ≥35 weeks Group 1= 10 mg zinc gluconate salt	Incidence of hyperbilirubinaemia (STB ≥ 15 mg/dL) STB levels at 72± 12 h of age.	The incidence of hyperbilirubinaemia was 26 % and 27 % in zinc and placebo group respectively.
Garg et al	10 Randomized controlled trial were included	2 in preterm neonates And 8 in term neonates	Reduction in bilirubin levels Effect on stool frequency	massage therapy helps in reducing bilirubin levels by vagal stimulation that increases stool frequency
Moghadam et al/2012	40 New born were recruited and allocated into two groups	**Control group** received conventional treatment **Massage group** 20 minutes massage therapy with almond oil, twice daily for four days.	Transcutaneous bilirubin. And Stool frequency	Massage therapy can prevent excessive bilirubin elevation and reduces need of phototherapy and exchange transfusion
Samra Nashwa M. et	50 new born were Recruited and divided into two groups	**Intervention group** neonates received Kangaroo mother care 3 times daily, a skin to skin contact was maintained with their mothers for 1 hour/session **Control group** -neonates received standard NICU care only	Total direct bilirubin Stool frequency	This study concluded that the group that received KMC reduced bilirubin levels in shorter time as compared to neonates in control group.

Lin C et al	56 neonates with jaundice	**Massage group** – received twice a day starting on the first day of phototherapy, using sweet almond oil for 15-20 mins/ session **Control group** neonates received only phototherapy	Breast feeding frequency Stool frequency	The study concluded that the frequency of defecation was higher in neonates who received massage therapy along with phototherapy as compared to neonates in control group
Chen J et al	69 full term inborn	**Treatment group –** baby massage was given for 15 -20 mins twice daily before 1 hour after morning and midday feed, from first day to fifth day postnatal. **Control group** normal regular care was given	Transcutaneous bilirubin level Total Serum bilirubin level Stool frequency	They concluded that massage therapy at early stage after birth reduces the bilirubin levels.
Eghbalian et al.	134 patients were recruited and randomly	**Massage group** - Gentle Massage was given for 15 -20 mins twice daily by the mother using baby oil. **Control Group** – phototherapy only.		Study proved massage therapy combined with phototherapy is effective in reducing the level of total bilirubin in less than 4 days
Seyyedrasooli et al.	43 healthy term infants	**Vimala massage**- 15-minute session of Vimala massage was given to healthy newborns. **Control group**- receive routine care	TcB, Meconium frequency were measured every morning.	The study concluded that after the intervention of 4 days although significant difference in TSB was not seen but a significant the trend of increase was lower in

				intervention group as compared to control group
Massaro et al.	147 healthy preterm neonates will be allocated into three group.	**Massage therapy Group** -massage given alone **Kinesthetic stimulation** Massage with kinesthetic stimulation is given **Control group**	Weight gain	The study concluded that there was maximum weight gain observed in group receiving massage therapy along with kinaesthetic stimulation

3.0 Methodology

3.1 Study Design:

Two group pretest- posttest control group design

3.2. Study setting:

Neonatal Intensive Care Unit (NICU)

3.3 Study Location

Multi Centre study

3.4 Study Participants

Neonates with hyperbilirubinaemia will be recruited

3.4 Sample size:

N= 94, With anticipated effect size of 0.8 and 30 % drop out sample size was calculated to be 47 in each group.

3.5 Selection Criteria

3.5.1 Inclusion criteria

3.5.1.1. New born in Neonatal Intensive Care Unit

3.5.1.2. Stable vitals

3.5.1.3. Preterm neonates

3.5.1.4. Gestational age < 37 weeks

3.5.1.5. Birth weight -1000 - 3500 g

3.5.1.6. APGAR Score at birth of 8 -10

3.5.1.7. Total serum bilirubin levels > 10 mg/dL

3.5.2. Exclusion Criteria

3.5.2.1. Neonates with congenital deformities

3.5.2.2. Neonates with gastro intestinal obstruction and biliary atresia

3.5.2.3. Sepsis

3.5.2.4. Neonates with ventilatory support

3.6 Outcome Measures

3.6.1. Total serum bilirubin

3.6.2. Transcutaneous Bilirubin

3.6.3. Weight

3.7. Procedure

3.7.1 Ethical Statement

This study has been approved by research advisory committee of Maharishi Markandeshwar Institute of Physiotherapy and rehabilitation, Maharishi Markandeshwar (Deemed to be University) and ethical clearance has been taken from an Institutional ethical committee of Maharishi Markandeshwar (Deemed to be University) IEC 2155. The study protocol has been registered in clinicaltrials.gov Protocol Results System (PRS) with ID NCT05077787 on 14 October 2021 and Unique Protocol ID: U1111-1269-9921 [42]. The study will be done according to the Helsinki declaration revised in 2013 and the National Ethical Guidelines for Biomedical Research involving Human participants, 2017.

3.7.2. Recruitment

The study design of the study is pretest – posttest control group design. Convenience Sampling will be used for recruiting the neonates. An informed consent form will be taken from the parents of neonates. Birth details of neonates such as gender, gestational age, corrected gestational age, occipitofrontal circumference, APGAR score and weight at the time of birth, will be taken from the records of neonate maintained in file. The Study will include neonates with hyperbilirubinaemia admitted in NICU at age < 48 hours, and will be selected according to the block randomization with 11*9 blocks with 9 blocks empty and will be allocated into two groups in 1: 1 ratio using sequentially, numbered, opaque, sealed and stapled envelopes (SNOSE).[36,43]

3.7.3 Procedure

Experimental group – neonates will receive tactile and kinaesthetic stimulation will be given in three phases for 15 minutes regularly for 3 consecutive days, in first phase massage therapy will be given for 5 minutes, in second phase kinaesthetic stimulation will be given for five minutes and in third phase techniques of massage therapy will be repeated , just after an hour of feeding the neonate twice daily[33], Control group – neonates will receive Phototherapy alone with other NICU care. Total serum bilirubin will be taken every day before treatment by nursing staff drawn from capillary site such as heel prick of a new born

Transcutaneous bilirubin will be measured from unexposed sites[44] using Bilicheck transcutaneous bilirubinometer such as glabellar region of forehead - just above the internasal area that is covered by eye mask, from a point over the Anterior superior iliac spine[45] and from the sternum just at level of manubrium sterni[46] and then average will be taken for these three readings, the transcutaneous bilirubinometer is kept in contact with the skin vertically on the

neonate's skin and weight will be measured using weighing machine before the first session and at the end of the 3rd session.

3.7.3.1 Experimental group

3.7.3.1.1. Phototherapy

Blue light double lamp phototherapy will be given to neonates and they will be placed naked in an incubator with eyes covered with eye mask and genitals covered with diaper in both groups along with regular NICU care. According to guidelines of AAP, there will be a distance of 20 cm – 30 cm between the surface on which neonate is lying and the light source with light intensity of 10 – 15 μW/cm^2/nm.

Tactile and kinaesthetic stimulation will be given for 15 minutes in three phases i.e., 1st phase massage therapy will be given for 5 minutes, in 2nd phase kinaesthetic stimulation will be given for 5 minutes, then again massage therapy will be given for 5 minutes.

3.7.3.1.2. Massage Therapy

Therapist will wash hands and sanitize, and also warm hands by rubbing them together and keeping it under radiant warmer before giving massage therapy to the neonates. Massage therapy will be given after 1 hour after evening feed for consecutive 3 days. Phototherapy will be stopped while therapist is giving intervention.[33]

Stroking

Massage with moderate pressure[38] will be given to the neonates. In supine lying position, stroking will be given on face by therapist using fingers pads of all four fingers of both hands together simultaneously for giving strokes on both sides of face from forehead to chin for 20 seconds i.e. 4 strokes in each 5 seconds i.e., 16 strokes for 20 seconds. 8 Strokes will be given using fingers pads moving from midline of chest towards side of thorax on bilateral side

simultaneously for 10 seconds i.e. 4 strokes in each 5 seconds. 8 strokes will be given on the abdomen in vertically downwards direction for 10 seconds, 4 strokes in each 5 seconds. 5 Strokes will be given for 20 seconds in prone position from proximal to distal direction i.e., starting from a line between spine of scapula on both sides to an imaginary line between posterior superior iliac spine, using finger pad simultaneously on bilateral side of vertebral column.

Kneading

Kneading will be given in supine lying position, pressure is exerted using finger pads of index, middle and ring finger slightly bent and are moved in circular motions as 4 ‘o’clock to 1 ‘o’clock clock position with left hand and 8 ‘o’clock to 11‘o’clock position with right hand over face 6 kneads in 5 seconds will be repeated twice on the forehead and cheek region, using both hands simultaneously on bilateral sides, flat finger kneading will be given using palmar surface of second to fourth digit on chest and abdomen 6 kneads will be given in 20 seconds starting from second costoclavicular space, then at nipple level, then just two fingers below nipple level, then at the level of lower ribs, then at level on the both sides of an imaginary line from umbilicus, and then in both inguinal regions. In prone position stroking will be given, using finger pad kneading will be given in 4 ‘o’clock to 1 ‘o’clock clock position with left hand and 8 ‘o’clock to 11‘o’clock position with right hand simultaneously 6 kneads in 20 seconds will be given on bilateral sides starting from intrascapular area, then at the medial side of inferior angle of scapula, then following the same direction downwards kneading will be given until an imaginary line drawn between two posterior superior iliac spine (PSIS).

3.7.3.1.2.3. Rolling

In supine lying position, for 20 seconds over the abdomen starting from area just below the lower ribs and skin will be rolled from midline towards the sides by holding skin with index

and middle finger on one side and thumb abducted on other side of both hands then adduct the thumb and pushing the skin towards the fingers, where the palm should lift off gradually but fingers tips contact should be maintained with the skin this procedure will be repeated on either side of spine from midline to side up to the imaginary line drawn from both ASIS. In prone lying position, rolling will be given for 20 seconds on back starting from the intrascapular area skin rolling will be directed from sides of vertebral column towards the sides and this procedure will be repeated on either side of spine from midline to side.

3.7.3.1.2.4 Tapping

In supine lying position tapping will be given for 10 seconds, all over the face starting from forehead towards chin, using finger pads of index, middle and ring finger it is given simultaneously in a rhythmic fashion. Tapping for 20 seconds will be given over abdomen using finger pad of index finger, middle finger and ring finger singly in a rhythm. In prone lying position tapping for 20 seconds will be given over the back on both side of the spine from upper back to vertically downwards direction.

3.7.3.1.2.5. Vibration

Vibration will be given using flat palmar surface of second to fifth digit involving movement in which muscles will be pressed and relaxed using up and down motion in rapid oscillatory movement of hand and minimal wrist flexion and extension with outstretched arm. It will be given in supine lying position over the chest for 10 seconds from area adjacent to manubrium of sternum towards the axillary region, then from area adjacent to body of sternum towards the axillary region then from just adjacent to xiphisternum to the sides on bilateral sides of sternum simultaneously. In abdomen vibration will be given for 10 seconds from umbilicus in the middle towards anterior superior iliac spine bilaterally using both hands together. Vibration over the back vibrations will be given starting from upper region – from intrascapular region

towards axillary region on bilateral sides then following the similar direction in prone lying position starting adjacent to vertebral column towards the sides of back upto area above the PSIS. Vibration will be given simultaneously bilaterally for 20 seconds.

3.7.3.1.2.6.Effleurage

Effleurage will be given on bilateral sides simultaneously. It will be given for 10 seconds, 1 stroke from under the chin, 1 stroke above the mouth, then 1 stroke from the point where nose starts and then 1 stroke from the forehead, thus will be drain the just below the ear into the subauricular glands this will be repeated twice. Effleurage will be given for 10 seconds strokes will be given on the chest from center line towards the axillary region, to drain the lymph into axillary lymph nodes and for 10 seconds strokes will be given over the abdomen starting from lower ribs towards the midline ending in groin region, to drain the lymph into superficial inguinal lymph node. Effleurage will be given on the back starting from neck, strokes will be given for 5 seconds with flat fingers from sides of neck and drained into supraclavicular glands, then 5 strokes will be given starting from spine of scapula towards axilla for 5 seconds and 10 strokes will be given from lower back towards the axilla to drain the lymph into the axillary lymph nodes for 10 seconds.

3.7.3.1.2.7. Tactile stimulation

For tactile stimulation will be given for 3 consecutive days twice a day, consisting of passive movements in following sequence:

1) Shoulder joint –flexion extension – 6 repetitions in 30 seconds for each limb, 2) Elbow joint – flexion extension 6 repetitions in 30 seconds for each limb, 2) Hip joint - flexion extension 6 repetitions in 30 seconds for each limb 3) knee joint - flexion extension 6 repetitions in 30 seconds for each limb and for both legs – 6 times flexion and extension of both limbs for 1 minute.[37]

3.7.3.2. Control Group

Phototherapy will be given to neonates along with regular NICU care. Blue light double lamp phototherapy will be given to neonates and they will be placed naked in an incubator with eyes and genital covered in both groups along with regular NICU care. According to AAP distance of between the surface on which neonate is lying and the light source will be about 30 cm with light intensity of 10 - 14μW/cm^2/nm.

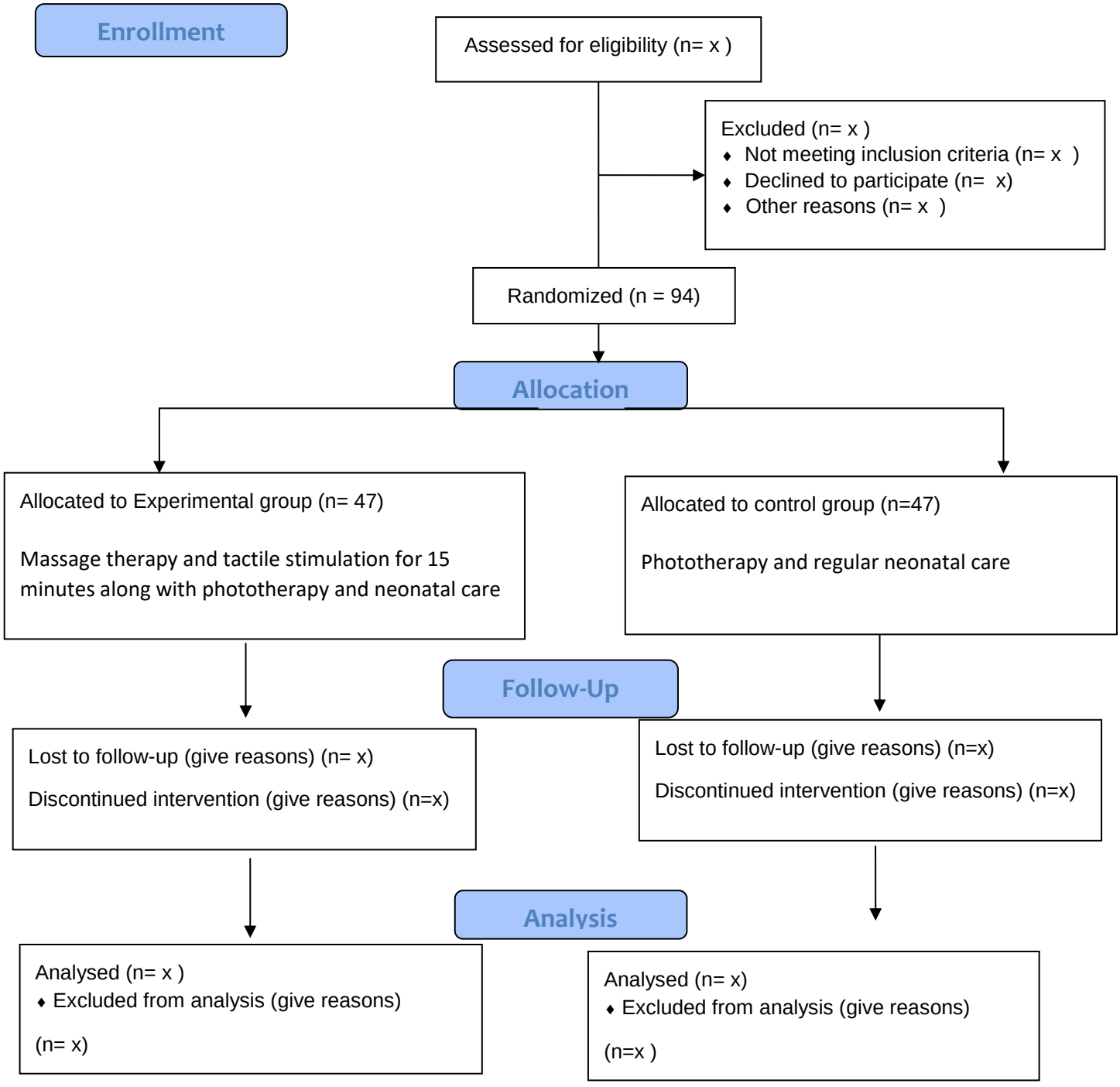
Enrollment
Assessed for eligibility (n= x)
Excluded (n= x)
♦ Not meeting inclusion criteria (n= x)
♦ Declined to participate (n= x)
♦ Other reasons (n= x)
Randomized (n = 94)
Allocation
Allocated to Experimental group (n= 47)
Massage therapy and tactile stimulation for 15 minutes along with phototherapy and neonatal care
Allocated to control group (n=47)
Phototherapy and regular neonatal care
Follow-Up
Lost to follow-up (give reasons) (n= x)
Discontinued intervention (give reasons) (n=x)
Lost to follow-up (give reasons) (n=x)
Discontinued intervention (give reasons) (n=x)
Analysis
Analysed (n= x)
♦ Excluded from analysis (give reasons)
(n= x)
Analysed (n= x)
♦ Excluded from analysis (give reasons)
(n=x)

Fig 3.1: Blue print of study

Table 3.1: Summary of Massage Intervention

Area	Technique	Treatment time/Repetitions
Face	In supine lying position, stroking will be given on face by therapist using fingers pads of all four fingers of both hands together simultaneously for giving strokes on both sides of face from forehead to chin for 20 seconds.	4 strokes in each 5 seconds i.e., 16 strokes for 20 seconds X 2
	Kneading will be given in supine lying position for 20 seconds pressure is exerted using finger pads of index, middle and ring finger slightly bent and are moved in circular in circular motions using finger tips in 4 'o'clock to 1 'o' clock position with left hand and 8 'o'clock to 11'o'clock position with right hand	6 kneads in 5 seconds on the forehead and cheek region, using both hands simultaneously of bilateral side X 2
	Tapping -In supine lying position, all over the face starting from forehead towards chin, using finger pads of index, middle and ring finger it is given simultaneously in a rhythmic fashion	tapping will be given for 5 seconds X 2
	Effleurage - It will be given for 10 seconds, 1 stroke from under the chin, 1 stroke above the mouth, then 1 stroke from the point	5 seconds X 2

	where nose starts and then 1 stroke from the forehead, thus will be drain the just below the ear into the subauricular glands	
Chest and Abdomen	Stroking - 8 Strokes will be given using fingers pads moving from midline of chest towards side of thorax on bilateral side simultaneously for 10 seconds i.e. 4 strokes in each 5 seconds. 8 strokes will be given on the abdomen in vertically downwards direction for 10 seconds, 4 strokes in each 5 seconds	10seconds 4 strokes in 5 seconds X 2
	In supine lying position flat finger kneading will be given using palmar surface of second to fourth digit on chest and abdomen 6 kneads will be given in 20 seconds starting from second costoclavicular space, then at nipple level, then just two fingers below nipple level, then at the level of lower ribs, then at level on the both sides of an imaginary line from umbilicus, and then in both inguinal regions	10 seconds X 2
	Rolling - In supine lying position, for 20 seconds over the abdomen starting from area just below the lower ribs and skin will be rolled from midline towards the sides by holding skin with index and middle finger on one side and thumb abducted on other side of both hands then adduct the thumb and pushing the skin towards the fingers, where the palm should lift off gradually but fingers tips contact should be maintained with the skin this procedure will be repeated on either side of spine from midline to side upto the imaginary line drawn from both ASIS	10 seconds X 2

	Tapping - Tapping for 20 seconds will be given over abdomen using finger pad of index finger, middle finger and ring finger singly in a rhythm.	10 seconds X 2
	Vibration - It will be given in supine lying position over the chest for 10 seconds from area adjacent to manubrium of sternum towards the axillary region, then from area adjacent to body of sternum towards the axillary region then from just adjacent to xiphisternum to the sides on bilateral sides of sternum simultaneously. In abdomen vibration will be given for 10 seconds from umbilicus in the middle towards anterior superior iliac spine bilaterally using both hands together	10 seconds X 2
	Effleurage for 20 seconds chest will be given from center line towards the nipple and effleurage will be given from midline towards the groin region	10 seconds X 2
Back	Stroking- In prone position Strokes will be given for 20 seconds from proximal to distal direction i.e., from intrascapular region to an imaginary line between posterior superior iliac spine, using finger pad simultaneously on bilateral side of vertebral column.	10 seconds X 2
	In prone position stroking will be given, using finger pad kneading will be given in 4 ‘o’clock to 1 ‘o’clock clock position with left hand and 8 ‘o’clock to 11‘o’clock position with right hand simultaneously 6 kneads in 20 seconds will be given on bilateral sides starting from intrascapular area, then at the medial aside of inferior angle of scapula, then following the same direction	10 seconds 3 kneads each 5 sec X 2

	downwards kneading will be given uptill an imaginary line drawn between two PSIS.	
	Rolling - In prone lying position, rolling will be given for 20 seconds on back starting from the intrascapular area skin rolling will be directed from sides of vertebral column towards the sides and this procedure will be repeated on either side of spine from midline to side.	10 seconds X 2
	Tapping - In prone lying position tapping for 20 seconds will be given over the back on both side of the spine from upper back to vertically downwards direction.	10 seconds X 2
	Vibrations – In abdomen vibration will be given for 10 seconds from umbilicus in the middle towards anterior superior iliac spine bilaterally using both hands together	10 seconds X 2
	Effleurage will be given for 20 seconds from the center or spine towards the axillary region	10 seconds X 2

	STUDY PERIOD					
	Enrolment	**Allocation**	**Post-allocation(treatment)**			**Close-out**
TIMEPOINT**	t_0	t_0	t_0	t_1	t_2	t_3
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
[GA, CGA, OFC, BW and APGAR]	X					
Allocation		X				
INTERVENTIONS:						
[Experimental Group]			←	—	—	→
[Control Group]			←	—	—	→
ASSESSMENTS:						
[Total serum bilirubin levels]	X		X	X	X	X
[Transcutaneous Bilirubin]	X		X	X	X	X
[Weight]	X		X	X	X	X

Fig 3.2: Schedule of enrolment, interventions, and assessments of the study

3.7.4. Outcome Measures

3.7.4.1. Total Serum Bilirubin - Total serum bilirubin will be measured daily. New born with total bilirubin levels more than 5 mg/dl and with rate of rise of > 0.5 mg/dl/h in first 24 hours, ≥ 12mg/dl on second day, ≥ 15mg/dL on day 3, ≥17 mg/dL on fourth and fifth day are known to have Hyperbilirubinaemia.[47]

3.7.4.2Transcutaneous Bilirubin - Transcutaneous bilirubinometer is a non- invasive and effective tool for screening Hyperbilirubinaemia in neonates with total serum bilirubin levels more than 3.39 mg/dl with reasonable sensitivity and specificity, will be measured using bilirubin meter, measurement will be taken from glabellar region of forehead - just above the internasal rea that is covered by eye mask, from a point over the Anterior superior iliac spine[45] and from the center of gluteal region covered by diaper[48,49] and then average will be taken for these three readings, the transcutaneous bilirubinometer is kept in contact with the skin vertically on the neonate's skin. TcB will be measured every 6 hr. Normative value of transcutaneous bilirubin neonates those requires phototherapy are 3.80mg/dl in 0-1 hour i.e between 75 percentile to 95 percentile of nomogram and after 54 hours it crossed the line of 95 percentile with mean TcB value of 13.76mg/dL. In first 12 hours the rate of rise of TcB is 0.22 mg/dL.[50] Avg TcB levels correlates TSB levels in newborns with gestational age ≥28 weeks significantly (r = 0.72) showing the reliability of TcB, as TSB is the gold standard of measuring bilirubin levels in neonates.[45]Thus it could be used as an alternative for frequent blood samples.[51]TSB values were > 5mg/dL were correlated to TcB values >5 mg/dL with 100 % sensitivity and 83% specificity.[52]

3.7.4.3. Weight gain

Weight gain will be measured using weighing scale.

3.7.5. Data Analysis

Data will be analyzed using IBM SPSS version 20. Normality will be checked using Shapiro - Wilk and Kolmogorov Smirnov test. If data will be normally distributed Repeated Measure Anova will be used within the group and independent t test will be used between the group and descriptive statistics will be expressed in Mean ± S.D and if data will not be normally distributed Friedman test will be used and between the group Mann – Whitney U test will be used and descriptive statistic will be expressed as Median and IQR. Post hoc analysis will be done using G-power software

4.0. Discussion

The aim of the present study is to assess the effect of tactile and kinaesthetic stimulation on neonates with hyperbilirubinaemia as an adjunct to phototherapy to reduce the bilirubin levels. The results similar to previous studies that have proved that massage therapy along with phototherapy helped in reducing the bilirubin levels in neonates with Hyperbilirubinaemia.[17] Also previous studies have shown effectiveness of tactile and kinaesthetic stimulation in increasing the weight of preterm neonates and also decreased the duration of hospital stay of neonates.[37] The expected outcomes of the study tactile and kinaesthetic stimulation in addition to phototherapy would be revealed at the end of the study.

4.1. Limitations

4.1.1. Study was not blinded as intervention was given by the researcher.

4.1.2. Absence of follow up

4.2. Strength of the study

4.2.1. To best of our knowledge present study will be the first study to prove the effectiveness of tactile and kinaesthetic stimulation in reducing the bilirubin levels.

4.2.2. Multicenter study

4.3. Further recommendations –

Further studies could be done with stratified according to subcategory of preterm

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6.0 Annexures

Annexure 1 Ethical Certificate

INSTITUTIONAL ETHICAL COMMITTEE

MAHARISHI MARKANDESHWAR INSTITUTE OF MEDICAL SCIENCES & RESEARCH
MULLANA, AMBALA

Communication of Decision of the Ethics Committee (IEC)

Project No: IEC- 2155

Project Title: Tactile and kinaesthetic stimulation in preterm neonates with hyperbilirubinaemia
Name of Student/Scholar: Saumya Kothiyal
Name of Institution: MMIPR, MULLANA (AMBALA)
☒ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): 13-10-2021 Date of previous review, if revised application: ----------
Decision of the Ethics Committee: ☒ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Remarks: Approved
Recommended for a period of : 1 year

Please note *

- **Inform EC immediately in case of any adverse events and serious adverse events.**
- **Inform EC in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to EC.**
- **Members of EC have right to monitor the trial with prior intimation.**

Signature of Member Secretary
Ethics Committee
MMIMSR

Member Secretary
Institutional Ethical Committee
M.M. Institute of Medical Sciences
& Research, Mullana (Ambala)

ANNEXURE 2: Informed Consent (English)

Informed consent is for parents of preterm neonates.

Principal Investigator – Dr. Saumya Kothiyal (PT)

Name of Organization – Maharishi Markandeshwar (Deemed to be University)

Under supervision of – Dr. Asir John Samuel

This consent form has two parts

- **Part I: Information Sheet (to share information about the study with you)**
- **Part II: Certificate of consent (for signature if you agree that your child may participate)**

Part I: Information Sheet

Introduction

I, Saumya Kothiyal doing research to define the effect of massage and movement of limbs in reducing the bilirubin levels in your preterm neonate with hyperbilirubinaemia. I am going to give you information and invite you on behalf of your new born to be part of this research. Before participating in study, you can talk to anyone you feel comfortable with about the research.

Purpose of research – The purpose of this study is to determine the effect of massage and moving limbs in reducing bilirubin levels in your preterm neonate with hyperbilirubinaemia.

Type of Research Intervention – This research will help in improving the gut mobility and increasing the stool frequency, thus leading to easier and faster excretion of bilirubin.

Participant Selection

The Study will include preterm neonates with hyperbilirubinaemia within age group > 48 hours old and admitted in Neonatal Intensive Care Unit with Gestational age <37 weeks and birth weight 1000 - 3500 g and total serum bilirubin levels <10 mg/dL.

Voluntary Participation – The participation in the study is voluntary and it is completely your choice, if you want your child to participate in the study or not. I also assure your refusal would not affect the care and other treatments your child/infant is receiving in NICU.

Procedure and Protocol

A. Unfamiliar procedures

The newborns will be selected according to the selection criteria and will be allocated into two groups by block randomization. and will be selected according to the block randomization with 11*9 blocks with 9 blocks empty and will be allocated into two groups using sequentially, numbered, opaque, sealed and stapled envelopes (SNOSE).

B. Description of procedure

If the total bilirubin levels of your new born admitted in NICU is higher than 10 mg/dL and if he /she will fulfill other selection criteria, they will be recruited in the study. And will be allocated in two groups. In one group neonates will receive phototherapy as well as massage therapy and movements of limbs in three phases, in first phase massage therapy will be given for five minutes, in second phase movement therapy will be given for five minutes and in third phase techniques of massage therapy will be repeated for five minutes, just after an hour of feeding the neonate in evening and in another group, neonates will receive phototherapy alone with conventional NICU care.

Duration

In intervention group neonates will receive massage therapy along with movement of the limbs for a duration of 15 minutes after 1 hour of feed in evening regularly for 3 consecutive days. Phototherapy will be stopped while massage therapy is given by therapist. Neonates recruited in group 2 will receive phototherapy along with conventional neonatal care for 3 days.

Side effects:

There will be no side effect of this intervention.

Risks:

There is no risk as it is non-invasive treatment.

Discomfort:

As in this study non-invasive methods, no discomfort will be experienced by neonates.

Benefits:

The treatment given in this study will help in early reduction of bilirubin levels and therefore will help in reducing the duration of hospital stay of neonates.

Reimbursement

You will not be given any incentive for participating in the study.

Confidentiality

The information of your child will be kept confidential.

Sharing the results

The result of the research work and improvement you child must be informed to you. However, identity concealment will not be guaranteed. Recorded videos may also be shared to maintain the authenticity.

The result of the study must be disseminated through publication, conference presentations and for that purpose, photographs your child may be used keeping the identity of your child blinded.

Right to refuse or withdraw

If you do not involve your child further in the study, you have your right or wish to refuse or withdraw from the study anytime.

If you have any question regarding, the study you can ask anytime.

Contact information:

Dr. Saumya Kothiyal (PT),
Phone no. 8650987709
Email: saumyakothiyal28@gmail.com

Part II: Certificate of consent

I have been invited on behalf of my child to participate in the study and I have been informed about the physiotherapy intervention to be given in the study. I have no objection for the use of massage and movement therapy for my child and also, I am giving my consent for sharing the result and photography of my child with his/her identity blinded.

Name of the participant _____

Signation of participant's family member /relative _____

(With relation)

Date: _____

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well. I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of parent

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done. I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

ANNEXURE 3

सूचित सहमति नवजात शिशुओं के माता-पिता के लिए है ।

प्रधान अन्वेषक - डॉ. सौम्या कोठियाल (पी.टी)

संगठन का नाम - महर्षि मार्कंडेश्वर (डीम्ड टू बी विश्वविद्यालय)

की देखरेख में - डॉ असिर जॉन सैमुवल

इस सहमति फार्म के दो भाग हैं ।

भाग I: सूचना पत्र (आप के साथ अध्ययन के बारे में जानकारी साझा करने

के लिए)

भाग II: सहमति प्रमाण पत्र (हस्ताक्षर के लिए यदि आप सहमत हैं कि

आपका बच्चा भाग ले सकता है)

भाग I:सूचना पत्र

परिचय

मैं, सौम्या कोठियाल, पीलिया से पीड़ित आपके अपरिपक्व नवजात शिशु में बिलीरुबिन के स्तर को, अंगों की मालिश

और उनके हिलाने के प्रभाव से कम करने पर अनुसंधान कर रही हूं । मैं आपको जानकारी देने जा रही हूं और आपको

अपने अपरिपक्व नवजात शिशु की ओर से इस शोध का हिस्सा बनने के लिए आमंत्रित करने जा रही हूं । अध्ययन में

भाग लेने से पहले, आप किसी को भी अनुसंधान के बारे में जिसे सहज महसूस करे बात कर सकते हैं ।

अनुसंधान का उद्देश्य : इस अध्ययन का उद्देश्य पीलिया से पीड़ित आपके अपरिपक्व नवजात शिशु में बिलीरुबिन के

स्तर को कम करने में मालिश और अंग हिलाने के प्रभाव को निर्धारित करना है

अनुसंधान उपचार का प्रकार - इस शोध से आंत की गतिशीलता में सुधार लाने और मल की आवृत्ति बढ़ाने में मदद

मिलेगी और बिलीरुबिन का आसानी और तेजी से उत्सर्जन होगा।

प्रतिभागी चयन:

अध्ययन में 48 घंटे की आयु से अधिक एनआईसीयू में भर्ती पीलिया से पीड़ित अपरिपक्व नवजातों को

शामिल किया जाएगा और नवजात गहन चिकित्सा इकाई में 37 सप्ताह की

गर्भावधि आयु

के पहले पैदा हुए नवजात शिशु जिसकावजन -1000 – 3500 ग्राम के बीच है और कुल सीरम बिलिरुबिन स्तर >

10mg/dL I

स्वैच्छिक भागीदारी - अध्ययन में भागीदारी स्वैच्छिक है और यह पूरी तरह से आपका

निर्णय है, यदि आप चाहते हैं कि अपरिपक्व नवजात शिशु अध्ययन में भाग ले या नहीं। मैं

यह भी विश्वास दिलाती हूं कि आपका इनकार आपके अपरिपक्व नवजात शिशु की

देखभाल और अंय उपचार को प्रभावित नहीं करेगा.

प्रक्रिया और प्रोटोकॉल:

अ: अपरिचित प्रक्रियाएं :

नवजात शिशुओं को चयन मानदंडों के अनुसार चुना जाएगा और ब्लॉक यादृच्छिककरण द्वारा दो समूहों में आवंटित किया जाएगा। और 9 ब्लॉक खाली के साथ 11 * 9 ब्लॉकों के साथ ब्लॉक यादृच्छिकता के अनुसार चुना जाएगा और अनुक्रमिक रूप से, क्रमांकित, अपारदर्शी, सील और स्टेपल लिफाफे का उपयोग करके दो समूहों में आवंटित किया जाएगा।

ब प्रक्रिया का विवरण :

यदि एनआईसीयू में भर्ती अपरिपक्व नवजात शिशु का कुल बिलीरुबिन स्तर 5 मिलीग्राम/डीएल से अधिक है और यदि

वह अन्य चयन मानदंडों को पूरा करेगा, तो उन्हें अध्ययन में भर्ती किया जाएगा और दो समूहों में आवंटित किया

जाएगा। एक समूह में अपरिपक्व नवजात शिशुओं को फोटोथेरेपी के साथ-साथ मालिश चिकित्सा और अंगों उनके

हिलाने के तीन चरणों में प्राप्त होगी, पहले चरण में मालिश चिकित्सा पांच मिनट के लिए दी जाएगी, दूसरे चरण में

आंदोलन चिकित्सा पांच मिनट के लिए दी जाएगी और तीसरे चरण में मालिश चिकित्सा की तकनीक पांच मिनट के

लिए दोहराई जाएगी, अपरिपक्व नवजात शिशु को दो बार दैनिक और एक अन्य समूह खिलाने के एक घंटे बाद नवजात

शिशुओं को अन्य एनआईसीयू देखभाल के साथ केवल फोटोथेरेपी प्राप्त होगी।

अवधि : एक समूह में भर्ती अपरिपक्व नवजातों को मालिश थेरेपी और अंगों को हिलाने की तकनीक नियमित रूप से शाम
को फीड के 1 घंटे बाद लगातार 3 दिन तक दी जाएगी. जबकि दूसरे समूह में भर्ती

अपरिपक्व नवजातों को 3 दिनों तक केवल

फोटोथेरेपी मिलेगी।

दुष्प्रभाव: इस अध्ययन का कोई दुष्प्रभाव नहीं होगा ।

जोखिम: इस अध्ययन में कोई जोखिम नहीं है क्योंकि यह गैर-आक्रामक उपचार है।

असुविधा: इस अध्ययन में गैर-आक्रामक तरीकों के रूप में, अपरिपक्व नवजात

शिशुओं द्वारा कोई असुविधा का अनुभव नहीं किया जाएगा।

लाभ: इस अध्ययन में दिए गए उपचार से बिलीरुबिन के स्तर को जल्दी कम करने में

मदद मिलेगी और इसलिए अपरिपक्व नवजात शिशुओं के अस्पताल में रहने की अवधि

को कम करने में मदद मिलेगी।

क्षतिपुर्ति: इस अध्ययन में भाग लेने के लिए आपको कोई प्रोत्साहन नहीं दिया जाएगा।

गोपनीयता:आपके अपरिपक्व नवजात शिशु की जानकारी गोपनीय रखी जाएगी।

परिणामों को साझा करना:

शोध कार्य और सुधार के परिणाम आपको सूचित किया जाएगा।हालांकि, पहचान छिपाने की गारंटी नहीं दी जाएगी। प्रामाणिकता बनाए रखने के लिए रिकॉर्ड किए गए वीडियो भी साझा किए जाएंगे। अध्ययन के परिणाम को प्रकाशन, सम्मेलन प्रस्तुतियों के माध्यम से प्रसारित किया जाएगा और उस उद्देश्य के लिए, आपके अपरिपक्व नवजात शिशु की तस्वीरों का उपयोग पहचान छिपा कर किया जा सकता है ।

मना करने का अधिकार :यदि आप अपने अपरिपक्व नवजात शिशु को अध्ययन में आगे शामिल नहीं करते हैं, तो

आपको अधिकार है आप कभी भी अध्ययन के लिए मना कर सकते हैं ।

यदि आपके मन में अध्ययन के बारे में कोई सवाल है, आप कभी भी पूछ सकते हैं ।

संपर्क जानकारी: डॉ सौम्या कोठियाल (पीटी),

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सहमति का भाग द्वितीय : प्रमाण पत्र

मुझे अपने नवजात शिशु की ओर से अध्ययन में भाग लेने के लिए आमंत्रित किया गया है और मुझे अध्ययन में दिए जाने वाले फिजियोथेरेपी के बारे में सूचित किया गया है। मैं अपने बच्चे के लिए मालिश और अंगों के हिलाने चिकित्सा के उपयोग के लिए कोई आपत्ति नहीं है और यह भी मैं परिणाम और उसकी पहचान बिना दिखाए अपने बच्चे की फोटोग्राफी साझा करने के लिए अपनी सहमति दे रहा/ रही हूं ।

प्रतिभागी का नाम _____

प्रतिभागी के परिवार के सदस्य /रिश्तेदार का नाम

_____

(रिलेशन के साथ)

दिनांक: _____

यदि अनपढ़, एक साक्षर गवाह हस्ताक्षर करना चाहिए (यदि संभव हो, तो इस व्यक्ति को प्रतिभागी द्वारा चुना जाना चाहिए और अनुसंधान टीम से कोई संबंध नहीं होना चाहिए)। जो प्रतिभागी अनपढ़ हैं, उन्हें अपने अंगूठे के प्रिंट को भी शामिल करना चाहिए । मैं संभावित भागीदार के माता पिता के लिए सहमति फार्म का सटीक पढ़ने देखा है, और व्यक्ति को सवाल पूछने का अवसर मिला है । मैं इस बात की पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से सहमति दी है।

माता-पिता के गवाह _____ अंगूठे का निशान

गवाह के हस्ताक्षर दिनांक_____

दिन/माह/वर्ष

शोधकर्ता द्वारा बयान/सहमति लेने वाले व्यक्ति मैंने नवजात शिशु के माता-पिता को सूचना पत्र में लिखा सही ढंग से जानकारी दी है, और वे समझ चुके हैं यह सुनिश्चित किया है । मैं इस बात की पुष्टि करता हूं कि माता-पिता को अध्ययन के बारे में प्रश्न पूछने का अवसर दिया गया था, और माता-पिता द्वारा पूछे गए सभी प्रश्नों का सही उत्तर दिया गया है और मेरी अनुसार सर्वोत्तम उत्तर दिया गया है । मैं इस बात की पुष्टि करता हूं कि व्यक्ति को सहमति देने के लिए बाध्य नहीं किया गया है, और सहमति स्वतंत्र रूप से और स्वेच्छा से दी गई है । इस आईसीएफ की एक प्रति तिभागी को उपलब्ध कराई गई है। _____

अनुमति लेने वाले शोधकर्ता/व्यक्ति का नाम_____

अनुमति लेने वाले शोधकर्ता/व्यक्ति के हस्ताक्षर _____

दिनांक_____

दिन/माह/वर्ष

ANNEXURE 3

ਸੂਚਿਤ ਸਹਿਮਤੀ

ਸੂਚਿਤ ਸਹਿਮਤੀ ਸਮੇਂ ਤੋਂ ਪਹਿਲਾਂ ਦੇ ਨਵਜਾਤ ਬੱਚਿਆਂ ਦੇ ਮਾਪਿਆਂ ਲਈ ਹੈ।

ਮੁੱਖ ਜਾਂਚਕਰਤਾ – ਡਾ. ਸੌਮਿਆ ਕੋਠਿਆਲ (PT)

ਸੰਗਠਨ ਦਾ ਨਾਮ - ਮਹਾਰਿਸ਼ੀ ਮਾਰਕੰਡੇਸ਼ਵਰ (ਡੀਮਡ ਟੂ ਬੀ ਯੂਨੀਵਰਸਿਟੀ)

ਦੀ ਨਿਗਰਾਨੀ ਹੇਠ – ਡਾ. ਅਸੀਰ ਜੌਹਨ ਸੈਮੂਅਲ

ਇਸ ਸਹਿਮਤੀ ਫਾਰਮ ਦੇ ਦੋ ਭਾਗ ਹਨ

- **ਭਾਗ I: ਜਾਣਕਾਰੀ ਸ਼ੀਟ (ਤੁਹਾਡੇ ਨਾਲ ਅਧਿਐਨ ਬਾਰੇ ਜਾਣਕਾਰੀ ਸਾਂਝੀ ਕਰਨ ਲਈ)**

- **ਭਾਗ I: ਸਹਿਮਤੀ ਦਾ ਸਰਟੀਫਿਕੇਟ (ਦਸਤਖਤਾਂ ਵਾਸਤੇ ਜੇ ਤੁਸੀਂ ਸਹਿਮਤ ਹੁੰਦੇ ਹੋ ਕਿ ਤੁਹਾਡਾ ਬੱਚਾ ਭਾਗ ਲੈ ਸਕਦਾ ਹੈ)**

ਭਾਗ I: ਜਾਣਕਾਰੀ ਸ਼ੀਟ

ਜਾਣ-ਪਛਾਣ

ਮੈਂ, ਸੌਮਿਆ ਕੋਠਿਆਲ, ਮਸਾਜ ਥੈਰੇਪੀ ਅਤੇ ਅੰਗਾਂ ਦੀ ਹਰਕਤ ਦੇ ਪ੍ਰਭਾਵ ਨੂੰ ਪਰਿਭਾਸ਼ਿਤ ਕਰਨ ਲਈ ਖੋਜ ਕਰ ਰਹੀ ਹਾਂ i ਹਾਈਪਰਬਿਲੀਰੂਬਿਨੇਮੀਆ ਨਾਲ ਤੁਹਾਡੇ ਸਮੇਂ ਤੋਂ ਪਹਿਲਾਂ ਦੇ ਨਵਜਾਤ ਬੱਚੇ ਵਿੱਚ ਬਿਲੀਰੂਬਿਨ ਦੇ ਪੱਧਰ ਨੂੰ ਘਟਾਉਂਦੀ ਹਾਂ। ਮੈਂ ਤੁਹਾਨੂੰ ਜਾਣਕਾਰੀ ਦੇਣ ਜਾ ਰਿਹਾ ਹਾਂ ਅਤੇ ਤੁਹਾਡੇ ਨਵੇਂ ਜਨਮੇ ਬੱਚੇ ਦੀ ਤਰਫ਼ੋਂ ਤੁਹਾਨੂੰ ਇਸ ਖੋਜ ਦਾ ਭਾਗ ਬਣਨ ਦਾ ਸੱਦਾ ਦੇਣ ਜਾ ਰਿਹਾ ਹਾਂ। ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਤੋਂ ਪਹਿਲਾਂ, ਤੁਸੀਂ ਕਿਸੇ ਵੀ ਅਜਿਹੇ ਵਿਅਕਤੀ ਨਾਲ ਗੱਲ ਕਰ ਸਕਦੇ ਹੋ ਜਿਸ ਨਾਲ ਤੁਸੀਂ ਸਹਿਜ ਮਹਿਸੂਸ ਕਰਦੇ ਹੋ।

ਖੋਜ ਦਾ ਮਕਸਦ – ਇਸ ਅਧਿਐਨ ਦਾ ਮਕਸਦ ਹਾਈਪਰਬਿਲੀਰੂਬੀਨੀਆ ਨਾਲ ਤੁਹਾਡੇ ਸਮੇਂ ਤੋਂ ਪਹਿਲਾਂ ਦੇ ਨਵਜਾਤ ਬੱਚੇ ਵਿੱਚ ਬਿਲੀਰੂਬਿਨ ਦੇ ਪੱਧਰਾਂ ਨੂੰ ਘੱਟ ਕਰਨ ਵਿੱਚ ਮਸਾਜ ਥੈਰੇਪੀ ਅਤੇ ਗਤੀਸ਼ੀਲ ਅੰਗਾਂ ਦੇ ਪ੍ਰਭਾਵ ਦਾ ਪਤਾ ਲਾਉਣਾ ਹੈ।

ਇੰਟਰਵੈਨਸ਼ਨ ਦੀ ਕਿਸਮ – ਇਹ ਖੋਜ ਅੰਤੜੀਆਂ ਦੀ ਗਤੀਸ਼ੀਲਤਾ ਵਿੱਚ ਸੁਧਾਰ ਕਰਨ ਅਤੇ ਟੱਟੀ ਦੀ ਬਾਰੰਬਾਰਤਾ ਨੂੰ ਵਧਾਉਣ ਵਿੱਚ ਮਦਦ ਕਰੇਗੀ, ਜਿਸ ਨਾਲ ਬਿਲੀਰੂਬਿਨ ਦਾ ਆਸਾਨੀ ਨਾਲ ਅਤੇ ਤੇਜ਼ੀ ਨਾਲ ਨਿਕਾਸ ਹੋਵੇਗਾ।

ਭਾਗੀਦਾਰ ਚੋਣ

ਅਧਿਐਨ ਵਿੱਚ 72 ਘੰਟਿਆਂ ਦੀ ਉਮਰ ਦੇ < ਉਮਰ ਸਮੂਹ ਦੇ ਅੰਦਰ ਹਾਈਪਰਬਿਲੀਰੂਬਿਨੇਮੀਆ ਵਾਲੇ ਨਵਜਾਤ ਜੋ ਸਮੇਂ ਤੋਂ ਪਹਿਲਾਂ ਦਾ ਹੈ ਸ਼ਾਮਲ ਹੋਣਗੇ ਅਤੇ 3of 7 weeks gestationਉਮਰ ਦੇ ਨਾਲ ਨੀਓਨਟਲ ਇਨਟੈਨਸਿਵ ਕੇਅਰ ਯੂਨਿਟ ਵਿੱਚ ਦਾਖਲ ਕੀਤਾ ਜਾਵੇਗਾ ਤੇ ਜਨਮ ਸਮੇਂ ਦਾ ਭਾਰ 1800 - 2500 ਗ੍ਰਾਮ ਅਤੇ ਕੁੱਲ ਸੀਰਮ ਬਿਲੀਰੂਬਿਨ ਦਾ ਪੱਧਰ 5mg/dL > ਸ਼ਾਮਲ ਹੋਵੇਗਾ।

ਸਵੈਇੱਛਤ ਭਾਗੀਦਾਰੀ – ਅਧਿਐਨ ਵਿੱਚ ਭਾਗੀਦਾਰੀ ਸਵੈ-ਇੱਛਤ ਹੈ ਅਤੇ ਇਹ ਪੂਰੀ ਤਰ੍ਹਾਂ ਤੁਹਾਡੀ ਚੋਣ ਹੈ, ਜੇ ਤੁਸੀਂ ਚਾਹੁੰਦੇ ਹੋ ਕਿ ਤੁਹਾਡਾ ਬੱਚਾ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲਵੇ ਜਾਂ ਨਾ। ਮੈਂ ਇਹ ਵੀ ਭਰੋਸਾ ਦਿਵਾਉਂਦੀ ਹਾਂ ਕਿ ਤੁਹਾਡਾ ਇਨਕਾਰ ਉਸ ਸੰਭਾਲ ਅਤੇ ਹੋਰ ਇਲਾਜਾਂ ਨੂੰ ਪ੍ਰਭਾਵਿਤ ਨਹੀਂ ਕਰੇਗਾ ਜੋ ਤੁਹਾਡੇ ਬੱਚੇ/ਬਾਲ NICU ਵਿੱਚ ਪ੍ਰਾਪਤ ਕਰ ਰਹੇ ਹਨ।

ਕਾਰਵਾਈ ਅਤੇ ਪਰੋਟੋਕਾਲ

C. ਅਣਜਾਣ ਪ੍ਰਕਿਰਿਆਵਾਂ

[illegible] [illegible] [illegible] [

ਮਿਆਦ:

ਇੰਟਰਵੈਨਸ਼ਨ ਗਰੁੱਪ ਦੇ ਨਵਜਾਤ ਬੱਚਿਆਂ ਵਿੱਚ ਅਸੀਂ ਲਗਾਤਾਰ 3 ਦਿਨ ਤੱਕ ਬਕਾਇਦਾ ਤੌਰ 'ਤੇ ਸ਼ਾਮ ਨੂੰ 1 ਘੰਟੇ ਦੀ ਖੁਰਾਕ ਲੈਣ ਦੇ ਬਾਅਦ 15 ਮਿੰਟਾਂ ਦੀ ਮਿਆਦ ਵਾਸਤੇ ਅੰਗਾਂ ਦੀ ਹਿੱਲਜੁੱਲ ਦੇ ਨਾਲ-ਨਾਲ ਮਸਾਜ ਥੈਰੇਪੀ ਦੇਵਾਂਗੇ। ਜਦ ਅਸੀਂ ਮਾਲਿਸ਼ ਚਿਕਿਤਸਾ ਦੇਵਾਂਗੇ, ਤਾਂ ਫੋਟੋਚਿਕਿਤਸਾ ਨੂੰ ਬੰਦ ਕਰ ਦਿੱਤਾ ਜਾਵੇਗਾ। ਦੂਜੇ ਗਰੁੱਪ ਵਿੱਚ ਭਰਤੀ ਕੀਤੇ ਨਵਜਾਤ ਬੱਚਿਆਂ ਨੂੰ 3 ਦਿਨਾਂ ਵਾਸਤੇ ਫੋਟੋਚਿਕਿਤਸਾ ਪ੍ਰਾਪਤ ਹੋਵੇਗੀ।

ਅਣਚਾਹੇ ਅਸਰ:

ਇਸ ਇੰਟਰਵੈਨਸ਼ਨ ਦਾ ਕੋਈ ਮਾੜਾ ਅਸਰ ਨਹੀਂ ਹੋਵੇਗਾ।

ਜੋਖਿਮ:

ਇਸਦਾ ਕੋਈ ਖਤਰਾ ਨਹੀਂ ਹੈ ਕਿਉਂਕਿ ਇਸ ਵਿੱਚ ਟਿਸ਼ੂਆਂ ਦਾ ਚੀਰ-ਫਾੜ ਸ਼ਾਮਲ ਨਹੀਂ ਹੈ

ਬੇਆਰਾਮੀ:

ਜਿਵੇਂ ਕਿ ਹੋਰ ਅੰਦਰੂਨੀ ਪ੍ਰਕਿਰਿਆਵਾਂ ਵਿੱਚ ਹੁੰਦਾ ਹੈ, ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਨਵਜਾਤ ਬੱਚਿਆਂ ਨੂੰ ਕਿਸੇ ਬੇਆਰਾਮੀ ਦਾ ਤਜ਼ਰਬਾ ਨਹੀਂ ਹੋਵੇਗਾ

ਫਾਇਦੇ:

ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਦਿੱਤਾ ਗਿਆ ਇਲਾਜ ਬਿਲੀਰੂਬਿਨ ਦੇ ਪੱਧਰਾਂ ਨੂੰ ਜਲਦੀ ਘੱਟ ਕਰਨ ਵਿੱਚ ਮਦਦ ਕਰੇਗਾ ਅਤੇ ਇਸ ਕਰਕੇ ਇਹ ਨਵਜਾਤ ਬੱਚਿਆਂ ਦੇ ਹਸਪਤਾਲ ਵਿੱਚ ਠਹਿਰਨ ਦੀ ਮਿਆਦ ਨੂੰ ਘੱਟ ਕਰਨ ਵਿੱਚ ਮਦਦ ਕਰੇਗਾ।

ਮੁੜ-ਭੁਗਤਾਨ:

ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਵਾਸਤੇ ਤੁਹਾਨੂੰ ਕੋਈ ਅਦਾਇਗੀ ਨਹੀਂ ਦਿੱਤੀ ਜਾਵੇਗੀ

ਗੁਪਤਤਾ:

ਤੁਹਾਡੇ ਬੱਚੇ ਦੀ ਜਾਣਕਾਰੀ ਨੂੰ ਗੁਪਤ ਰੱਖਿਆ ਜਾਵੇਗਾ।

ਨਤੀਜਿਆਂ ਨੂੰ ਸਾਂਝਾ ਕੀਤਾ ਜਾਵੇਗਾ

ਖੋਜ ਕਾਰਜ ਅਤੇ ਤੁਹਾਡੇ ਬੱਚੇ ਵਿੱਚ ਸੁਧਾਰ ਦੇ ਨਤੀਜੇ ਬਾਰੇ ਤੁਹਾਨੂੰ ਸੂਚਿਤ ਕਰਨਾ ਲਾਜ਼ਮੀ ਹੈ। ਪਰ, ਪਛਾਣ ਛੁਪਾਉਣ ਦੀ ਗਰੰਟੀ ਨਹੀਂ ਦਿੱਤੀ ਜਾਵੇਗੀ। ਪ੍ਰਮਾਣਿਕਤਾ ਨੂੰ ਬਣਾਈ ਰੱਖਣ ਲਈ ਰਿਕਾਰਡ ਕੀਤੀਆਂ ਵੀਡੀਓਜ਼ ਨੂੰ ਵੀ ਸਾਂਝਾ ਕੀਤਾ ਜਾ ਸਕਦਾ ਹੈ। ਅਧਿਐਨ ਦੇ ਨਤੀਜੇ ਨੂੰ ਲਾਜ਼ਮੀ ਤੌਰ 'ਤੇ ਪ੍ਰਕਾਸ਼ਨਾ, ਕਾਨਫਰੰਸ ਪੇਸ਼ਕਾਰੀਆਂ ਰਾਹੀਂ ਵੰਡਿਆ ਜਾਣਾ ਚਾਹੀਦਾ ਹੈ ਅਤੇ ਇਸ ਮਕਸਦ ਵਾਸਤੇ, ਤੁਹਾਡੇ ਬੱਚੇ ਦੀਆਂ ਫੋਟੋਆਂ ਨੂੰ ਤੁਹਾਡੇ ਬੱਚੇ ਦੀ ਪਛਾਣ ਨੂੰ ਗੁਪਤ ਰੱਖਦੇ ਹੋਏ ਵਰਤਿਆ ਜਾ ਸਕਦਾ ਹੈ।

ਇਨਕਾਰ ਕਰਨ ਜਾਂ ਪਿੱਛੇ ਹਟਣ ਦਾ ਅਧਿਕਾਰ

ਜੇ ਤੁਸੀਂ ਅਧਿਐਨ ਵਿੱਚ ਅੱਗੇ ਜਾਕੇ ਆਪਣੇ ਬੱਚੇ ਨੂੰ ਸ਼ਾਮਲ ਨਹੀਂ ਕਰਦੇ , ਤਾਂ ਤੁਹਾਡੇ ਕੋਲ ਆਪਣਾ ਅਧਿਕਾਰ ਹੈ ਜਾਂ ਤੁਸੀਂ ਕਿਸੇ ਵੀ ਸਮੇਂ ਅਧਿਐਨ ਤੋਂ ਇਨਕਾਰ ਕਰਨ ਜਾਂ ਪਿੱਛੇ ਹਟਣ ਦੀ ਇੱਛਾ ਕਰਦੇ ਹੋ।

ਜੇ ਇਸ ਦੇ ਸਬੰਧ ਵਿੱਚ ਤੁਹਾਡੇ ਕੋਈ ਸਵਾਲ ਹਨ, ਤਾਂ ਖੋਜਕਰਤਾ ਨੂੰ ਤੁਸੀਂ ਕਿਸੇ ਵੀ ਸਮੇਂ ਪੁੱਛ ਸਕਦੇ ਹੋ।

ਸੰਪਰਕ ਜਾਣਕਾਰੀ:

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ਭਾਗ II: ਸਹਿਮਤੀ ਦਾ ਸਰਟੀਫਿਕੇਟ

ਮੈਨੂੰ ਮੇਰੇ ਬੱਚੇ ਦੀ ਤਰਫ਼ੋਂ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਸੱਦਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂੰ ਅਧਿਐਨ ਵਿੱਚ ਦਿੱਤੀ ਜਾਣ ਵਾਲੀ ਸਰੀਰਕ-ਚਿਕਿਤਸਾ ਦਖਲਅੰਦਾਜ਼ੀ ਬਾਰੇ ਸੂਚਿਤ ਕਰ ਦਿੱਤਾ ਗਿਆ ਹੈ। ਮੇਰੇ ਬੱਚੇ ਵਾਸਤੇ ਮਾਲਿਸ਼ ਅਤੇ ਹਰਕਤ ਚਿਕਿਤਸਾ ਦੀ ਵਰਤੋਂ ਵਾਸਤੇ ਮੈਨੂੰ ਕੋਈ ਇਤਰਾਜ਼ ਨਹੀਂ ਹੈ ਅਤੇ ਨਾਲ ਹੀ ਮੈਂ ਆਪਣੇ ਬੱਚੇ ਦੇ ਨਤੀਜੇ ਅਤੇ ਫ਼ੋਟੋਗਰਾਫੀ ਨੂੰ ਉਸਦੀ ਪਛਾਣ ਨੂੰ ਅੱਖੋਂ ਪਰੋਖੇ ਕਰਕੇ ਸਾਂਝਾ ਕਰਨ ਵਾਸਤੇ ਆਪਣੀ ਸਹਿਮਤੀ ਦੇ ਰਹੀ/ਰਹੀ ਹਾਂ।

ਭਾਗੀਦਾਰ ਦਾ ਨਾਮ _____

ਭਾਗੀਦਾਰ ਦੇ ਪਰਿਵਾਰਕ ਮੈਂਬਰ/ਰਿਸ਼ਤੇਦਾਰ _____ **ਦਾ ਦਸਤਖਤ**

(ਸੰਬੰਧ ਦੇ ਨਾਲ)

ਮਿਤੀ: _ _____

ਜੇ ਅਨਪੜ੍ਹ ਹੈ

ਇੱਕ ਪੜ੍ਹੇ-ਲਿਖੇ ਗਵਾਹ ਨੂੰ ਲਾਜ਼ਮੀ ਤੌਰ 'ਤੇ ਦਸਤਖਤ ਕਰਨੇ ਚਾਹੀਦੇ ਹਨ (ਜੇ ਸੰਭਵ ਹੋਵੇ, ਤਾਂ ਇਸ ਵਿਅਕਤੀ ਨੂੰ ਭਾਗੀਦਾਰ ਦੁਆਰਾ ਚੁਣਿਆ ਜਾਣਾ ਚਾਹੀਦਾ ਹੈ ਅਤੇ ਇਸਦਾ ਖੋਜ ਟੀਮ ਨਾਲ ਕੋਈ ਸਬੰਧ ਨਹੀਂ ਹੋਣਾ ਚਾਹੀਦਾ)। ਭਾਗੀਦਾਰ ਜੋ ਅਨਪੜ੍ਹ ਹਨ ਉਨ੍ਹਾਂ ਨੂੰ ਆਪਣੇ ਅੰਗੂਠੇ ਦਾ ਪ੍ਰਿੰਟ ਵੀ ਸ਼ਾਮਲ ਕਰਨਾ ਚਾਹੀਦਾ ਹੈ। ਮੈਂ ਸਹਿਮਤੀ ਫਾਰਮ ਨੂੰ ਸੰਭਾਵੀ ਭਾਗੀਦਾਰ ਦੇ ਮਾਪੇ ਨੂੰ ਦਰੁਸਤ ਤਰੀਕੇ ਨਾਲ ਪੜ੍ਹਕੇ ਸੁਣਾਉਂਦੇ ਹੋਏ ਦੇਖਿਆ ਹੈ, ਅਤੇ ਵਿਅਕਤੀ ਵਿਸ਼ੇਸ਼ ਨੂੰ ਸਵਾਲ ਪੁੱਛਣ ਦਾ ਮੌਕਾ ਮਿਲਿਆ ਹੈ। ਮੈਂ ਪੁਸ਼ਟੀ ਕਰਦਾ ਹਾਂ ਕਿ ਵਿਅਕਤੀ ਵਿਸ਼ੇਸ਼ ਨੇ ਸੁਤੰਤਰਤਾ ਨਾਲ ਸਹਿਮਤੀ ਦਿੱਤੀ ਹੈ।

witness_____ ਦਾ ਨਾਮ ਅਤੇ ਮਾਪੇ ਦੇ ਅੰਗੂਠੇ ਦਾ ਪ੍ਰਿੰਟ ਪ੍ਰਿੰਟ ਕਰੋ

ਗਵਾਹ ਦੇ ਦਸਤਖਤ _____

ਮਿਤੀ _____

ਦਿਨ/ਮਹੀਨਾ/ਸਾਲ

ਖੋਜਕਾਰ/ਸਹਿਮਤੀ ਲੈਣ ਵਾਲੇ ਵਿਅਕਤੀ ਦੁਆਰਾ ਬਿਆਨ, ਮੈਂ ਸੰਭਾਵੀ ਭਾਗੀਦਾਰ ਦੇ ਮਾਪੇ ਨੂੰ ਸਟੀਕਤਾ ਨਾਲ ਜਾਣਕਾਰੀ ਸ਼ੀਟ ਪੜ੍ਹਕੇ ਸੁਣਾਈ ਹੈ, ਅਤੇ ਮੇਰੀ ਸਰਵੋਤਮ ਯੋਗਤਾ ਅਨੁਸਾਰ ਇਹ ਯਕੀਨੀ ਬਣਾਇਆ ਗਿਆ ਹੈ ਕਿ ਵਿਅਕਤੀ ਸਮਝਦਾ ਹੈ ਕਿ ਨਿਮਨਲਿਖਤ ਚੀਜ਼ਾਂ ਕੀਤੀਆਂ ਜਾਣਗੀਆਂ। ਮੈਂ ਪੁਸ਼ਟੀ ਕਰਦਾ/ਦੀ ਹਾਂ ਕਿ ਮਾਪੇ ਨੂੰ ਅਧਿਐਨ ਬਾਰੇ ਸਵਾਲ ਪੁੱਛਣ ਦਾ ਮੌਕਾ ਦਿੱਤਾ ਗਿਆ ਸੀ, ਅਤੇ ਮਾਪੇ ਵੱਲੋਂ ਪੁੱਛੇ ਗਏ ਸਾਰੇ ਸਵਾਲਾਂ ਦਾ ਜਵਾਬ ਸਹੀ ਤਰੀਕੇ ਨਾਲ ਅਤੇ ਮੇਰੀ ਸਰਵੋਤਮ ਯੋਗਤਾ ਅਨੁਸਾਰ ਦਿੱਤਾ ਗਿਆ ਹੈ। ਮੈਂ ਪੁਸ਼ਟੀ ਕਰਦਾ ਹਾਂ ਕਿ ਵਿਅਕਤੀ ਵਿਸ਼ੇਸ਼ ਨੂੰ ਸਹਿਮਤੀ ਦੇਣ ਲਈ ਮਜ਼ਬੂਰ ਨਹੀਂ ਕੀਤਾ ਗਿਆ ਹੈ, ਅਤੇ ਸਹਿਮਤੀ ਸੁਤੰਤਰਤਾ ਨਾਲ ਅਤੇ ਸਵੈ-ਇੱਛਾ ਨਾਲ ਦਿੱਤੀ ਗਈ ਹੈ। ਇਸ ICF ਦੀ ਇੱਕ ਨਕਲ ਭਾਗੀਦਾਰ ਨੂੰ ਪ੍ਰਦਾਨ ਕੀਤੀ ਗਈ ਹੈ।

ਖੋਜਕਰਤਾ/consent_____ ਲੈਣ ਵਾਲੇ ਵਿਅਕਤੀ ਦਾ ਨਾਮ ਲਿਖੋ

ਖੋਜਕਾਰ/consent_____ ਲੈ ਰਹੇ ਵਿਅਕਤੀ ਦੇ ਦਸਤਖਤ

ਮਿਤੀ _____

ਦਿਨ/ਮਹੀਨਾ/ਸਾਲ

ANNEXURE 5

Data Collection form

Name:

Age (days):

APGAR score:

Occipitofrontal circumference (centimeters):

Gestational age (weeks):

Vitals:

HR (Beats/ min)-

RR (Breaths/min)-

SpO2-

Birth weight (grams) –

Date of assessment -

Outcome measures:

Variable/Days	**1st Day**	**2nd Day**	**3rd Day**
Transcutaneous Bilirubin			
Total Serum bilirubin			
Weight Gain			

ANNEXURE 5

Plagiarism Report

Curiginal

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W	URL: https://www.researchgate.net/publication/285045211_Effects_of_baby_massage_on_neonatal_jaundice_in_healthy_Iranian_infants_A_pilot_study Fetched: 3/22/2020 6:27:47 AM	1
W	URL: https://www.researchgate.net/publication/284729227_Effects_of_infant_massage_on_jaundiced_neonates_undergoing_phototherapy Fetched: 1/18/2021 2:44:17 PM	1